M966N HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 2 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Hillel Backrach
Executive Vice-President
ESC Medical Systems, Ltd.
100 Crescent Road
Needham, Massachusetts 02194

Re: Derma™ 20 Laser System, K964253

Dear Mr. Backrach:

The Food and Drug Administration (FDA) has reviewed several press releases dated April 15, 1997 which were published by PR Newswire, and by Reuter's (New York and Tel Aviv) for ESC Medical System's Derma™ 20 Laser (Derma™ 20). The Derma™ 20 is manufactured by ESC Medical Systems. Ltd. (ESC) and is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our review of ESC's press releases revealed that the Derma™ 20 is being promoted for intended uses that have not been cleared by the agency i.e., skin resurfacing applications. This is exemplified by the following statement, "The Derma™ 20 is an advanced pulsed Er:YAG laser system used for general dermatological applications, including fast-growing skin resurfacing applications." Additionally, a telephone call placed to your firm on May 30, 1997 revealed a recording which promoted the Derma™ 20 laser for hair restoration, wrinkles, and scar removal.

FDA will permit manufacturers to announce in an initial press release that a specific device has been cleared/approved by FDA for the stated indications in the labeling. However, manufacturers who receive a general clearance for the use of a device may not narrow the indication(s) (objective intent) to specific medical procedures, disease states or conditions, without first submitting supporting data to the agency and receiving prior clearance.

The Derma™ 20 Laser System has been cleared under section 510(k) of the Act for the incision, excision, ablation, vaporization, and hemostasis of soft tissue. By making claims of

skin resurfacing, including hair restoration, wrinkle or scar removal, or similar claims, ESC has made a significant modification in the intended use of the device as promulgated under 21 CFR 807.81(a)(3)(ii), that requires the submission of a new 510(k) premarket notification.

Because of these changes, the Derma™ 20 Laser System is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Derma™ 20 Laser System is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the new intended use for the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Derma™ 20 Laser. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New England District Office (HFR-NE200), Stoneham, Massachusetts 02180.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

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